

**Amendment and Response**

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Serial No.: 10/052,032

Confirmation No.: 1581

Filed: 16 January 2002

For: PRESSURE SENSITIVE ADHESIVES HAVING QUARTERNARY AMMONIUM FUNCTIONALITY, ARTICLES, AND METHODS**Remarks**

The Office Action mailed 17 June 2004 has been received and reviewed. The pending claims are claims 1-51. Claims 16-24, 26, 34-43, 45-49, and 51 having been withdrawn from consideration, the claims currently under examination are claims 1-15, 25, 27-33, 44, and 50. Reconsideration and withdrawal of the rejections are respectfully requested.

**The 35 U.S.C. §103 Rejection**

The Examiner rejected claims 1-15, 25, 27-33, 44, and 50 under 35 U.S.C. §103(a) as being unpatentable over the Admitted Prior Art (APA) in view of Delgado et al. (U.S. Patent No. 5,908,693) and Perrault et al. (U.S. Patent No. 6,039,940). This rejection is respectfully traversed.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To establish a *prima facie* case of obviousness, three criteria must be met. First, the prior art reference (or references) must teach or suggest all of the claim limitations. Second, there must be some suggestion or motivation, either in the cited reference (or references), or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Third, there must be a reasonable expectation of success. M.P.E.P. § 2142 (citations omitted).

Applicants' Representatives do not fully understand the discussion of the allegedly "Admitted Prior Art" or the statement at the page 2, carryover to page 3, of the Office Action. Clarification is requested. Specifically, Applicants' Representatives do not fully understand the statement starting with "However, it would have been obvious in the art to incorporate an inherently anti-microbial polymerized acrylated quaternary ammonium monomer (i.e. a covalently bonded quaternary ammonium functionality) taught by Perrault et al to a meth(acrylate) PSA disclosed by the APA..." To the extent this is understood, Applicants' Representatives make the following comments.

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Applicants' invention is directed to a pressure sensitive adhesive composition that includes a pressure sensitive adhesive polymer of copolymerized monomers, wherein the pressure sensitive adhesive polymer includes covalently bonded quaternary ammonium functionality. The polymer includes at least one copolymerized monoethylenically unsaturated (meth)acrylic acid ester monomer, wherein the (meth)acrylic acid ester monomer, when homopolymerized, has a Tg of less than about 25°C, and at least one copolymerized monoethylenically unsaturated reinforcing monomer, wherein the reinforcing monomer, when homopolymerized, has a Tg of at least about 25°C. This is neither disclosed nor suggested in the prior art cited by the Examiner, whether allegedly "admitted" or not.

Delgado et al. disclose a pressure sensitive adhesive that includes low molecular weight quaternary ammonium compounds (e.g., cetyl dimethyl ethyl ammonium bormide, cetyl trimethyl ammonium bromide, myristyl trimethyl ammonium bromide; see, e.g., column 8, lines 47-57). Such compounds are not copolymerized into a pressure sensitive adhesive polymer. The quaternary ammonium compounds are a part of an antimicrobial system that includes an antimicrobial agent (e.g., the quaternary ammonium compound) and a transfer agent (see, e.g., column 8, lines 30-42). The transfer agent "permits the antimicrobial agent to migrate from the interior of the adhesive layer to the exposed surface where it can contact and control pathogens before they are introduced into the wound" (column 8, lines 39-42). In essence, Dalgado et al. teach that the antimicrobial agent needs to be mobile to be effective. Furthermore, there is no teaching or suggestion that an antimicrobial agent can be incorporated into a pressure sensitive adhesive polymer and maintain the effectiveness of the antimicrobial and the pressure sensitive adhesive. Thus, Delgado et al. teach away from immobilizing an antimicrobial agent into a pressure sensitive adhesive polymer.

Perault discloses a hydrogel that is inherently antimicrobial. Although the hydrogel dressings of Perault have an "adhesive quality" (column 3, lines 29-31), there is no teaching or suggestion of a pressure sensitive adhesive composition. Also, although the hydrogels of Perault

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include polymerized quaternary ammonium-containing monomers, thereby forming antimicrobial hydrogels, one of skill in the pressure sensitive adhesive art would not look to hydrogel art to modify a pressure sensitive adhesive. That is, one of skill in the art of pressure sensitive adhesives would not be led to incorporate a quaternary ammonium-containing monomer of the type used to make a Perault hydrogel into a pressure sensitive adhesive polymer. This is particularly true in view of Delgado et al. if an antimicrobial pressure sensitive adhesive composition is desired because Delgado et al. teach away from immobilizing an antimicrobial agent (e.g., a quaternary ammonium-containing monomer).

Furthermore, one skilled in the art would have no reasonable expectation whatsoever that the disclosure of Perault combined with the disclosure of Delgado et al. (with or without any allegedly "admitted" prior art) would necessarily provide the embodiments of the present invention as claimed by Applicant. Again, this is particularly true because Delgado et al. emphasize the need for a transfer agent to be used in combination with an antimicrobial agent to allow for migration of the antimicrobial agent within a pressure sensitive adhesive.

It is respectfully submitted that the combination of Delgado et al. and Perault (with or without any allegedly "admitted" prior art) in an obviousness rejection can only occur by the impermissible use of hindsight reasoning. In order to establish a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 at 93 ("Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, . . . was a legally improper way to simplify the difficult determination of obviousness."). One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." In re Gorman, 933 F.2d 982, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). Further, both the suggestion for combining the teachings of the prior art to make the invention and the reasonable likelihood of its success must be founded in the prior art and not in the teachings of Applicants' disclosure. In re

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Dow Chem., 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Here, the cited art neither suggests the combination of its teachings nor suggests the reasonable likelihood that such a combination would result in the present invention.

**Information Disclosure Statements**

Applicants' Representatives thank the Examiner for acknowledging that the previously submitted documents have been made of record. Since the 1449's have all been initialed by the Examiner, it is assumed that the Examiner also considered these documents.

In response to the Examiner's allegation that Applicants have not complied with the guidelines set forth in MPEP 2004 and the accusation of "cloaking [of] a clearly relevant reference," Applicants' Representatives respectfully disagree. Applicants have attempted to be as compliant with all requirements related to their duty of disclosure and have not attempted to "cloak" any relevant information.

To clarify, it is respectfully submitted that Applicants have no duty to explain the relevance of English language documents submitted in an Information Disclosure Statement, and Applicants may submit documents in an Information Disclosure Statement for any number of reasons:

The provisions of 37 CFR 1.97 and 37 CFR 1.98 provide a mechanism by which patent applicants may comply with the duty of disclosure provided in 37 CFR 1.56. Applicants and other individuals substantively involved with the preparation and/or prosecution of the patent application also may want the Office to consider information for a variety of other reasons.

M.P.E.P. §609 (8<sup>th</sup> Ed.).

Furthermore, the submission of a document in an Information Disclosure Statement is not an admission that the document is material to patentability:

Further, the filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR 1.56(b). 37 CFR 1.97(h).

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Also, the Examiner has a duty to consider documents submitted in an Information Disclosure Statement:

An information disclosure statement filed in accordance with the provisions of 37 CFR 1.97 and 37 CFR 1.98 will be considered by the Examiner assigned to the application. . . . Once the minimum requirements of 37 CFR 1.97 and 37 CFR 1.98 are met, the examiner has an obligation to consider the information. . . . The initials of the examiner placed adjacent to the citations on the PTO-1449 or PTO/SB/08A and 08B or its equivalent mean that the information has been considered by the examiner to the extent noted above.

**M.P.E.P. §609 (8<sup>th</sup> Ed.).**

Finally, based on the rules promulgated by the United States Patent and Trademark Office, the Examiner is obligated to consider and initial all the documents submitted by Applicants in an Information Disclosure Statement (regardless of the number):

Examiners must consider all citations submitted in conformance with the rules and this section, and their initials when placed adjacent to the considered citations on the list or in the boxes provided on a form PTO-1449 or PTO/SB/08A and 08B provides a clear record of which citations have been considered by the Office.

**M.P.E.P. §609(III)(C)(2) (8<sup>th</sup> Ed.).**

So, again Applicants thank the Examiner for initialing and returning the 1449 forms previously submitted. The Examiner is invited to contact Applicants' Representatives in the event that additional clarification is needed.

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It is respectfully submitted that the pending claims 1-51 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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Sept. 16, 2004  
Date

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 16<sup>th</sup> day of September, 2004, at 2:08 p.m. (Central Time).

By: Rachel Bagliardi-Gibson  
Name: Rachel Bagliardi-Gibson